AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Claim 1 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0% and an exo-methylene content of less than about ~~0.1~~ 0.01%.

Claim 2 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5% and an exo-methylene content of less than about ~~0.1~~ 0.01%.

Claim 3 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than about ~~0.1~~ 0.01%.

Claims 4-41 (canceled)

Claim 42 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.0% and an exo-methylene content of less than about ~~0.1~~ 0.01% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 43 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.5% and an exo-methylene content of less than about ~~0.1~~ 0.01% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 44 (currently amended) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than about ~~0.1~~ 0.01% prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 45 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.0% and an exo-methylene content of less than about ~~0.1~~ 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 46 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.5% and an exo-methylene content of less than about ~~0.1~~ 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

a) preparing a solution of ondansetron base in water;

b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 47 (currently amended) A pharmaceutical formulation comprising ondansetron hydrochloride dihydrate, wherein the ondansetron hydrochloride dihydrate has a purity of at least about 99.9% and an exo-methylene content of less than about ~~0.1~~ 0.01%, and wherein the ondansetron hydrochloride dihydrate is prepared by the process of:

a) preparing a solution of ondansetron base in water;

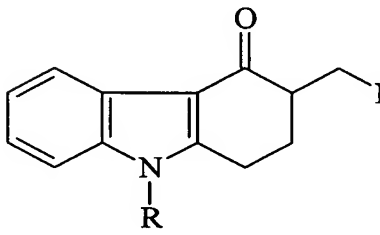
b) acidifying the solution with hydrogen chloride to form a precipitate;

c) washing the precipitate; and

d) crystallizing pure ondansetron hydrochloride dihydrate from water and in the presence of activated carbon.

Claim 48 (previously presented) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the ondansetron base is prepared by the process of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



(where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondansetron base from the solution;

d) washing the precipitate;

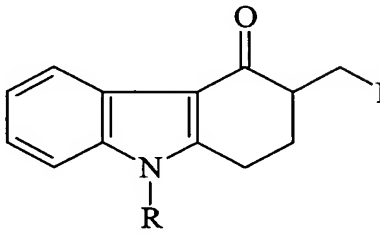
e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 49 (previously presented) Ondansetron hydrochloride dihydrate as in claim 42, 43, or 44, wherein the crystallization step is performed only once.

Claim 50 (previously presented) The pharmaceutical formulation comprising ondansetron hydrochloride dihydrate as in claim 45, 46, or 47, wherein the ondansetron base is prepared by the process of:

a) preparing a solution of methyl-imidazole and dimethylamino-methyl-carbazolone of the formula



$N(Me)_2$. HCl (where R = C_{1-4}, alkyl)

b) heating the solution;

c) removing a precipitate containing ondansetron base from the solution;

d) washing the precipitate;

e) drying precipitate to obtain ondansetron base;

wherein the solution of methyl-imidazole and dimethylamino-methyl-carbazolone is prepared by adding about 4 to about 6 equivalents methyl-imidazole to one equivalent dimethylamino-methyl-carbazolone.

Claim 51 (new) Ondansetron hydrochloride dihydrate having a purity of at least about 99.9% and an exo-methylene content of less than 0.1%.